



## Periodic Review / Retain Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Social Services
<b>Virginia Administrative Code (VAC) citation</b>	22 VAC 40-890-10 et seq.
<b>Regulation title</b>	Human Subject Research Regulations
<b>Document preparation date</b>	August 20, 2003

This form is used when the agency has done a periodic review of a regulation and plans to retain that regulation without change. This information is required pursuant to Executive Orders 21 (2002) and 58 (1999) ([governor.state.va.us/Press\\_Policy/Executive\\_Orders/EOHome.html](http://governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html)).

### Legal basis

*Please identify the state and/or federal source of legal authority for the regulation, including (1) the most relevant law and/or regulation, and (2) promulgating entity, i.e., the agency, board, or person. State that the Office of the Attorney General has certified that the entity continues to have the proper authority to promulgate this regulation.*

Sections § 63.1-25.01 and §§ 32.1-162.16 - 32.1-162.20 of the *Code of Virginia* establish the legal authority for the regulation. The Office of the Attorney General has certified that the Virginia Department of Social Services continues to have the proper authority to promulgate this regulation.

### Alternatives

*Please describe all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.*

As the regulation is required by the *Code of Virginia* and the regulation protects the safety and well-being of research subjects, no alternatives were considered.

### Public comment

*Please summarize all public comment received in response to the Notice of Periodic Review and provide the agency response. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.*

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No comments were received during the public comment period.

### Effectiveness

*Please indicate whether the regulation meets the criteria set out in Executive Order 21, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

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The Human Subject Research Regulations complies with Executive Order 21 because the regulation is mandated by Virginia law and the regulation protects public health, safety, and welfare. The regulation is written in a clear and concise manner so that it is understandable among a variety of local entities, contract agencies, customers, clients, and agencies, as required by Executive Order 21 that “Regulations shall be clearly written and easily understandable by the individuals and entities affected.”

### Result

*Please state that the agency is recommending that the regulation should stay in effect without change.*

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Because the Human Subject Research Regulation is legally mandated and protects the interests and rights of human subjects involved in research, the Virginia Department of Social Services recommends that the regulation should stay in effect without change.

### Family impact

*Please provide an analysis of the regulation’s impact on the institution of the family and family stability.*

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The Human Subject Research regulation protects the institution of the family by ensuring that the privacy of the family is protected. Specific methods for protecting the privacy of the family and

family members include: (a) assurance that participants provide informed consent, without undue inducement or coercion; (b) protection of research participants' identifying information; (c) informing research participants of expected risk and benefits, research procedures, and intended use of results; and (d) assurance to research participants that their participation is voluntary, and that their participation or non-participation does not affect their rights, benefits, or services.